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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,372	12/21/2001	Jeffrey A. Trogolo	A-035 US	5146

7590 06/25/2007  
AGION TECHNOLOGIES  
60 Audubon Road  
Wakefield, MA 01880

EXAMINER
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CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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06/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/032,372

Applicant(s)

TROGOLO ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,6,7,10-12,14-21,38,40-43,45,51-54,56,60,61,63 and 82-85 is/are pending in the application.
- 4a) Of the above claim(s)      is/are withdrawn from consideration.
- 5) ☐ Claim(s)      is/are allowed.
- 6) ☒ Claim(s) 2,3,6,7,10-12,14-21,38,40-43,45,51-54,56,60,61,63 and 82-85 is/are rejected.
- 7) ☐ Claim(s)      is/are objected to.
- 8) ☐ Claim(s)      are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on      is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No.     .
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>    </u>                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>    </u>  | 6) <input type="checkbox"/> Other: <u>    </u>                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/30/2007 has been entered.

The Examiner withdraws the 35 USC 103(a) rejections of Claims 2,3,6-7,10-12,14-21,38,40,42,45,51-54,56,60,61,63,84,85 over JP 4-66512, Marans et al. (US 4,403,083), Niira et al. (US Pat. 5,556,699) and Yukei et al. and claims 64,66-73,75-81 over JP 4-66512 in view of Takebayashi et al. (US Pat. 6,113,936) and WO 94/13726 in view of the claim amendment (5/30/2007) indicating that the hydrophilic polymer is "water absorbing, water vapor absorbing and wettable" and the Declarations (5/30/2007) providing evidence that JP 4-66512 teaches the use of encapsulating polymers which do not meet the above criteria.

### ***Election/Restrictions***

The examiner withdraws the election of species requirement. After Amendment (5/30/2007), claims 2,3,6-7,10-12,14-21,38,40-43,45,51-54,56,60,61,63,82-85 are pending with no claims withdrawn as directed to a non-elected invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1616

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,3,6-7,10-12,14-21,51,52,60,63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marans et al. (US 4,403,083), Niira et al. (US Pat. 5,556,699), Yukei et al. and Hudgin et al. (US Pat. 3,975,350).

Marans et al. disclose a hydrophilic polyurethane particles having a diameter of 0.1-100 mils which prepared by adding a resin reactant, which contains a prepolymer containing polyol and isocyanate, drop wise into an aqueous reactant there the volume ratio of water reactant to prepolymer can be infinite, but preferably in the range of 2-200:1 (Columns 2, lines 40-58, Column 3, lines 28-68, Columns 3-5, Column 6, lines 1-56). It is disclosed that because large amounts of water are in the aqueous reactant it is possible to combine a great variety of material sin the aqueous reactant which are otherwise not possible in limited water reacting systems (Column 6, lines 60-65). It is disclosed that a large amount of water soluble or water dispersible materials, such as zeolites, up to about 800% by weight of the amount of water can be added and by homogenously distributing these materials in the aqueous reactant it is possible to effect wide distribution of these materials throughout the finally prepared particle (Column 7, lines 15-29). It is disclosed that the additives can also be combined into the resin reactant, if desired (Column 7, lines 28-31). Further, it disclosed that the hydrophilic nature of the particles was tested by placing the particles in a chamber at 100% humidity for 3 days with the resulting increase in weight providing evidence that they were hydrophilic (Column 8, lines 35-68).

Niira et al. teach that antibiotic zeolites containing silver which further incorporate ammonium ions effectively prevent discoloration of resins into which the antibiotic zeolites are incorporated (Column 2, lines 11-23).

Art Unit: 1616

Yukei et al. disclose that sodium nitrate increased elution of silver from silver zeolite and was dose dependent (Abstract).

Hudgin et al. disclose a polymer system, including polyurethanes, in which the hydrophilicity of the polymer can be tailored to suit the particular requirements of the system and that the polymer system can be combined with active agents such as bacteriostats, fungicides and algacides (Column 1, Column 2). It is disclosed that the polymers have the desired properties of softness and when exposed to humid atmosphere or when wet, having excellent properties in the wet state, i.e. ranging from gel-like to polymer being compliant, soft and flexible; and in the dry state, from gel-like polymers to polymers which are machinable and polishable (Column 4, lines 30-40). It is disclosed that the polymer may have a water pickup in excess of 10%, preferably in excess of 20% (Column 11, lines 5-14). It is disclosed that the release rate may be tailored according to the water absorption rate of the polymer, diffusion path or wall thickness of the polymer surrounding the active ingredient and the amount of the active ingredient on a weight percent basis (Column 18, lines 13-18).

The prior art discloses the incorporation of zeolite into a hydrophilic polymer particle having a size of 0.1-100 mils. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose combining 10 to 1000 parts by weight of at least one ion-exchange type antimicrobial agent comprising a ceramic carrier and ion-exchanged antimicrobial agent comprising a ceramic carrier and ion-exchanged antimicrobial metal ions and 100 parts by weight of a hydrophilic polymer where the hydrophilic polymer is in the form of a microparticle having dispersed therein multiple particles of the at least one said antimicrobial agent and an average diameter size of about 15 to about 300 microns. However, the prior art amply suggests the same as the prior art discloses the preparation of hydrophilic polyurethane

Art Unit: 1616

particles having a size of 0.1-100 mils in which are dispersed zeolites and antimicrobial zeolites containing silver. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of antibacterial silver zeolites and hydrophilic polymers ranging within the sizes disclosed in the prior art would be effective as antimicrobials. Furthermore, it would have been well within the skill of one of ordinary skill in the art to vary the amount antimicrobial silver zeolite and hydrophilic polyurethane polymer, including within the ratios claimed, depending on the size of the hydrophilic polyurethane particle desired and effectiveness of antimicrobial activity desired.

Also, the prior art discloses the incorporation of ammonium ions to prevent discoloration and sodium nitrate increased the elution of silver ions from silver zeolite. As such, one of ordinary skill in the art would expect that addition of the same to the silver zeolite would prevent discoloration and increase elution of the silver ions from the silver zeolite.

The examiner has duly considered Applicant's arguments but deems them unpersuasive. The Applicant's arguments appear to be premised entirely on the JP 4-66512 reference. However, since the rejected claims herein are directed solely to the claimed antimicrobial hydrophilic polymer particle and not the same incorporated into a polymer matrix and JP 4-66512 is no longer part of the rejection, the rejection is maintained as indicated above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 64,66-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takebayashi et al. (US Pat. 6,113,936) and Hudgin et al. (US Pat. 3,975,350) for the reasons of record and the further reasons below.

Takebayashi et al. disclose a method of microencapsulating silver zeolite with polyurethane where the average diameter of the obtained microcapsule is usually from 0.1 to 300 micrometers, preferably from 0.5 to 200 micrometers, depending on the size of the core particle and the core particle is usually from 0.1 to 200 micrometers, preferably 0.5 to 100 micrometers (See entire reference, especially Column 2, lines 1-13, Column 3, line 9, Column 4, line 66, Column 5, lines 60-64). It is disclosed that the added amount of monomer polymerizable by condensation depends on the concentration of the solid substance, its surface area, its surface condition and the desired amount of the polymer and is usually 0.001 to 20 parts by weight, preferably 0.01 to 10 parts by weight based on one part by weight of said solid substance (Column 5, lines 16-21).

Hudgin et al. (US Pat. 3,975,350) is cited here for the same reasons as above and is incorporated herein to avoid repetition.

The prior art discloses a method of microencapsulating silver zeolite with polyurethane where the average diameter of the obtained microcapsule is usually from 0.1 to 300 micrometers, preferably from 0.5 to 200 micrometers, depending on the size of the core particle and the core particle is usually from 0.1 to 200 micrometers, preferably 0.5 to 100 micrometers. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose that the thickness of the hydrophilic polymer coating is from about 1 to about 15 microns within the coated particle having a mean average size of about 300 microns or less and a weight ratio of the antimicrobial agent to the hydrophilic polymer form from 1:100 to

Art Unit: 1616

1000:1000. However, the prior art amply suggests the same as the prior art discloses encapsulation of silver zeolite where the average diameter of the obtained microcapsule is usually from 0.1 to 300 micrometers, preferably from 0.5 to 200 micrometers, depending on the size of the core particle and the core particle is usually from 0.1 to 200 micrometers, preferably 0.5 to 100 micrometers, where the added amount of monomer polymerizable by condensation depends on the concentration of the solid substance, its surface area, its surface condition and the desired amount of the polymer and is usually 0.001 to 20 parts by weight, preferably 0.01 to 10 parts by weight based on one part by weight of said solid substance. Further, the prior art discloses that hydrophilic polyurethane polymer systems allow one to tailor release rates based on water absorption, diffusion path or wall thickness and weight percent of polymer and active ingredient. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of antibacterial silver zeolites and hydrophilic polymers ranging within the sizes and thickness disclosed in the prior art would be effective as antimicrobials.

The examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

#### ***Double Patenting***

Claims 2,3,6-7,10-12,14-21,38,40-43,45,51-54,56,60,61,63,82-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/336,699. Although the conflicting claims are



Art Unit: 1616

not identical, they are not patentably distinct from each other because the claims of copending Application No. 11/336,699 discloses a medical device containing an antimicrobial additive dispersed as a discrete particles in a polymer matrix where the antimicrobial additive comprises water absorbing, water vapor absorbing and wettable hydrophilic polymer having dispersed or encapsulated an antimicrobial agent comprising a metal antibacterial, including, for instance, ceramic carriers and ion-exchanged metal ions and the claims of the present application claim the additive and a polymer composition containing said additive dispersed in or encapsulated by said polymer where the antimicrobial is a ceramic carrier and ion-exchanged metal ion. The claims of the copending application claim the medical device as indicated above. The difference between the claims of the copending application and the present claims is that the claims of the copending application do not expressly disclose the antimicrobial polymer particle apart from the polymer matrix. However, the claims of the copending application amply suggest the same as the antimicrobial polymer particle is described as an additive. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to prepare the same as a separate unit apart from the polymer matrix with the expectation that the same would provide increased manufacturing flexibility in that the entire polymer composition would not have to be contemporaneously prepared and would allow various different polymer matrixes to be used when desired.

Therefore, the claimed invention, as a whole, would have been obvious modification of the claims of said copending application to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the claims of said copending application.

Art Unit: 1616

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Conclusion*

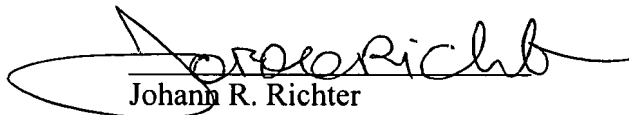
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
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June 21, 2007

  
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